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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,970	01/11/2002	Rami Lidor-Hadas	1662/55602	3018

26646 7590 04/08/2003

KENYON & KENYON  
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NEW YORK, NY 10004

EXAMINER

STOCKTON, LAURA

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 04/08/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.



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DATE MAILED:

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on January 13, 2003

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~which~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 1-47 are pending in the application.  
Of the above, claim(s) 4-41 are withdrawn from consideration.  
☐ Claim(s) is/are allowed.  
☒ Claim(s) 1-3 and 42-47 are rejected.  
☐ Claim(s) is/are objected to.  
☐ Claim(s) are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892  
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4-45 and 1  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

10/045,970

## DETAILED ACTION

Claims 1-47 are pending in the application.

### *Election/Restrictions*

Applicants' election without traverse of Group I in Paper No. 7 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Election was made **without** traverse in Paper No. 7.

In response to Applicants' remarks concerning rejoining Group IV with Group I, in accordance with M.P.E.P. §821.04 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims

with process claims commensurate in scope with the allowed product claims will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 42-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen {Zhongguo Yiyao Gongye Zazhi (1993), 24(6), pages 241-242}, Tyers {U.S. Pat. 4,845,115}, Coates et al. {U.S. Pat. 4,695,578} and Tyers {U.S. Pat. 4,835,173}, each taken alone or in combination with each other when similar utilities are asserted. An English translation of Chen will be referred to hereinafter.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Applicants claim Ondansetron hydrochloride dihydrate. Each of Chen {page 1, Compound (1) and page 2- section III}, Tyers '115 {column 3 and especially Example 2}, Coates et al. {column 4 and especially Example 10 in column 20} and Tyers '173 {column 3 and especially Example 2} teach Ondansetron hydrochloride dihydrate.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the instant claimed invention and the prior art is that the prior art is silent as to the purity of the product obtained

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

Changing the form, purity or other characteristic of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art. *In re Cofer*, 148 U.S.P.Q. 268 (CCPA 1966). Therefore, absent a showing of a viable unexpected, unobvious and superior properties, the instant claimed compound would have been suggested to one skilled in the art.

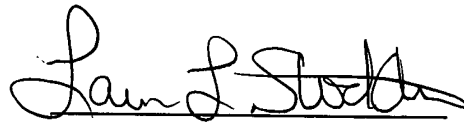
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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The fax phone number for the organization where this application  
or proceeding is assigned is (703) 308-4556.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

April 3, 2003